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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,114

12/05/2003

Scott A. Burton

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

01/04/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/729,114	Applicant(s) BURTON ET AL.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2, 5-12, and 14-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-12 and 14-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/23/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment, request for RCE, and IDS, all filed 10/23/2009.

Claims 3, 4, 13 have been canceled. Claims 29 and 30 have been added by after final amendment filed 10/08/2009.

Claims 1-2, and 5-12, 14-30 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2, 5-12, 14-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claims introduced new matter by reciting that "mineral oil in an amount effective to render the composition sufficiently nonadherent such that when coated on a substrate the nonadherent polymer composition displays a 180° peel strength from stainless steel of less than 1 N/cm." Plasticizer, mineral oils in particular, never disclosed by applicants to perform the claimed function. No effective amount of mineral oils has capable to perform the claimed function been disclosed by the present specification. The amount of mineral oils of "at least 60%" as claimed by claims 18, 29 and 30 is not disclosed anywhere in the present disclosure. In page 14, lines 1-2, applicant disclosed that: "The plasticizing agent is typically used in amounts of from about 1 to 2000 parts by weight per 100 parts of the hydrophobic polymer." Therefore, applicant disclosed wide range of the amount of plasticizer in relation to 100 parts of the polymer composition, and not "the mineral oil is present in an amount of at least 60 wt%, based on the total weight of the polymer composition. In table 2, page 24, applicant disclosed gel composition comprising 69% KAYDOL (mineral oil). However, this amount is only with 30% D1124K (very specific SIS polymer) and 1% IRGANOX 1010 (specific antioxidant), and this does not form at least 60% of the total weight of the polymer composition that further comprises 1-60%

micro particles. Further, the claimed "at least 60%" does not limit the amount of the mineral oils to 2000 parts as disclosed.

In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-2, 5-12, 14-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101, 103-107 of copending Application No. 10/728,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully

disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: wound dressing comprising aperture substrate and polymer composition comprising organic hydrophobic polymeric matrix, hydrophilic microparticles, and plasticizer, claimed by claim 15 of the copending application. The present claims and the conflicting claims of the copending application are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. The examiner acknowledged applicant's intention to provide an appropriate response to the double patenting rejection upon an indication of otherwise allowable subject matter and in the event this rejection is maintained. Therefore, the rejection is maintained.

7. Claims 1-2, 5-12, 14-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 94, 96-117 of copending Application No. 10/728,439. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common

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subject matter as follows: wound dressing comprising polymer composition comprising organic hydrophobic polymeric matrix, hydrophilic microparticles, bioactive agent, and mineral oil plasticizer, claimed by claims 95, 112 and 116 of the copending application. The difference between the present claims and the conflicting claims is that the present claims recite substrate. The substrate is known in the art of wound dressing, and one having ordinary skill in the art would have provided substrate to support the polymer matrix as evident by claim 117 of the copending application. The present claims and the conflicting claims of the copending application are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-2, 5-8, 12, 14-18, 20, 21, and 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento et al (EP 0512855, IDS filed 03/02/2009) in view of Lykke (WO 02/066087, IDS 05/12/2005).

Applicant Claims

Currently amended claim1 is directed to a wound dressing comprising an apertured liquid permeable substrate and an absorbent, nonadherent polymer composition comprising: a hydrophobic organic polymer matrix; 1 wt-% to 60 wt-% hydrophilic organic microparticles, which when in a nonhydrated form have an average particle size of 10 microns or less; and mineral oil in an amount effective to render the composition sufficiently nonadherent such that when coated on a substrate the

nonadherent polymer composition displays a 180° peel strength from stainless steel of less than 1 N/cm.

Currently amended claim 19 further recites that the hydrophobic organic polymer matrix comprises a styrene-isoprene-styrene copolymer, a styrene-butadiene-styrene copolymer, or mixtures thereof; and the hydrophilic microparticles comprising an amine-containing organic polymer.

Currently amended claim 20 further recites that the hydrophobic organic polymer matrix comprising a styrene-isoprene-styrene copolymer, a styrene-butadiene-styrene copolymer, or mixtures thereof; and the hydrophilic microparticles comprising sodium polyacrylate copolymer.

Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)

Cilento teaches an absorbent wound composition comprising a wound filler polymeric matrix comprising styrene radial or block type copolymers (i.e., hydrophobic thermoplastic elastomeric polymer) such as styrene-isoprene-styrene (page 3, lines 3-16), 5-40% mineral oil, and 25-75 wt % absorbing powders comprising absorbent polyacrylates which include salts of crosslinked polyacrylic acid and sodium polyacrylate (page 3, lines 37-43). Sodium polyacrylate is disclosed by applicant as the copolymer of sodium acrylate and acrylic acid in the present application page 8, lines 24-25. Powders are dry, i.e. nonhydrated. The reference teaches the polymeric matrix comprises secondary absorbent powders which read on additional additives claimed by claim 16

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(page 10, lines 32-42). The mineral oil functions as a plasticizer for the styrene radial or block copolymer component and also functions to increase the stretchability of the wound filler matrix (page 3, lines 17-18). The absorbent powders can absorb 500-1000% liquid of their original weight, implying that powder is dry (page 10, lines 15-17). Cilento teaches the use antimicrobial agents (page 3, line 48). Cilento teaches a method of wound healing which comprises placing the absorbent wound filler into the wound to absorb the exudates. The wound filler can be removed from the wound in one piece and does not cause wound injury on removal. The wound filler keeps the wound bed moist and produces in a wound an environment suitable for healing (page 2, lines 34-42). The polymer matrix disclosed by the reference is not disclosed as adhesive, rather soft plastic and lightly tacky (page 3, line 54). The wound filler can be covered by 4x4 (page 10, lines 11-12).

With regard to amount of mineral oils as claimed by claims 18, 29 and 30, Cilento teaches 5-40% mineral oils and further teaches the advantage of the mineral oils function as a plasticizer for the styrene radial or block copolymer component and also function to increase the stretchability of the wound filler matrix. Therefore, one having ordinary skill in the art would have determined the amount of the mineral oils in the composition according to the desired properties of the polymeric matrix.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Although Cilento desired to absorb wound exudates and further desired to cover the polymer matrix, however, the reference does not explicitly the apertured substrate. Cilento does not explicitly teach the particles size.

Lykke teaches medical article comprising a composition comprising a polymeric matrix and absorbent particles of microcolloid having particle sizes less than 10 microns (abstract; page 3, 7th paragraph; page 7, 1st paragraph; page 11, 3rd paragraph; page 12; page 28, claims 3 and 4), and preferably the particle size less than 1 micron (page 4). The smaller size particles influence the rheological properties of the article and are able to pass through narrow nozzles during production (page 7, 2nd and 3rd paragraphs). The microcolloid particles form from 5-100% by weight of the composition (page 5, 3rd paragraph). The particles are made of acrylic acid polymer (page 15, 1st paragraph; page 16, 4th paragraph). The particles are dry powder, i.e. nonhydrated (page 5, last paragraph). The composition further comprises a plasticizer (page 14, 3rd paragraph; page 18, 2nd paragraph). The polymeric matrix is preferably hydrophobic (page 6, 6th paragraph). The polymer matrix comprises S-EB-S as claimed by claim 25 (polystyrene-polyethylene/butylene-polystyrene), S-I-S and S-B-S copolymers (page 17, 5th paragraph). The composition is coated on porous substrate to form wound dressing that allows the wound exudates to pass through the layer quickly (page 9, 2nd and 3rd paragraphs). The matrix further comprises active agents including antibacterial agents (page 19, 3rd paragraph).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing polymer matrix comprising hydrophobic polymer, hydrophilic particles of polyacrylate and mineral oil plasticizer as taught by Cilento, and further add porous substrate as taught by Lykke. One would have been motivated to do so because Cilento desired remove wound exudates and further desired to cover the polymer matrix, and motivated by the teaching of Lykke that porous substrate forms wound dressing that allows the wound exudates to pass through the layer quickly. One would reasonably expect formulating wound dressing comprising polymer matrix comprising hydrophobic polymer, hydrophilic particles of polyacrylate and mineral oil plasticizer coated on a porous substrate that allows quickly passage of the wound exudates.

Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound filling polymer matrix comprising hydrophobic polymer, hydrophilic particles of polyacrylate and mineral oil plasticizer as taught by Cilento, and select the particles as small as less than 1 micron as taught by Lykke. One would have been motivated to do so because Lykke teaches that smaller size particles influence the rheological properties of the wound dressing and are able to pass through narrow nozzles during production. One would reasonably expect formulating wound dressing comprising polymer matrix comprising hydrophobic polymer, hydrophilic particles of polyacrylate having small sizes and mineral oil plasticizer, wherein the dressing has good rheological properties and easy to produce.

Claims 1 and 20 recite the properties of the composition that would be displayed when the composition is coated on a substrate and the composition of Cilento would also display those characteristic properties when coated on a substrate since Cilento does not teach the polymer matrix as adhesive and comprises the same hydrophobic polymer, hydrophilic particles and mineral oils.

With regard to claims 7 and 8, while Lykke teaches fine pore sizes of the porous substrate, it does not explicitly teach the number of the pores per square cm as claimed by claim 7 or pore size of 1 mm to 0.5 cm as claimed by claim 8. It is the examiner's position that the pore size and their number are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Evidence to support the examiner's position is found in Lykke's reference in page 10, 1st paragraph, where the reference teaches that porosity can be controlled and higher porosity is advantageous.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

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12. Claims 9-11, 19, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento in view of Lykke as applied to claims 1-2, 5-8, 12, 14-18, 20-21, 23-30 and further in view of the article "SALCARE[®] SC95" by Ciba[®].

The combined teachings of Cilento and Lykke are previously discussed as set forth in this office action.

Although Cilento teaches sodium polyacrylate and Lykke teaches varieties of materials of the microcolloidal particles including acrylic polymers, however, the references do not specifically teach the specific amine-containing polymers forming the microparticles as claimed by claims 9-11, 19, 22.

The article teaches that "SALCARE[®] SC95" is a cationic homopolymer dispersed in medicinal grade white oil. SALCARE[®] SC95 does not require pre-mixing or special equipment, has high thickening efficiency, and gives good uniform performance when incorporated in cosmetics.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing comprising porous substrate and polymer composition comprising a hydrophobic polymeric matrix and hydrophilic absorbent particles of acrylic acid polymers as taught by Cilento combined with Lykke, and replace the acrylic acid particles by SALCARE[®] SC95 particles taught by the article of Ciba[®]. One would have been motivated to do so because of the article of Ciba[®] teaches that such material does not require pre-mixing or special equipment, has high thickening efficiency, and gives good uniform performance when incorporated in cosmetics. One would reasonably expect formulating wound dressing comprising

porous substrate and polymer composition comprising a hydrophobic polymeric matrix and absorbent particles made of SALCARE[®] SC95 that is safe to the skin and easy to produce.

Response to Arguments

13. Applicant's arguments with respect to claims 1, 2, 5-12, 14-30 have been considered but are moot in view of the new ground(s) of rejection.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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